# IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

MICHAEL	and GABRIELA YONG,	)			
as Pare	nts, Guardians and	)			
Next of	Friends of	)			
Tiffany	Yong,	)			
		)			
	Plaintiffs,	)			
		)			
V.		)	Civ.	No.	02-147-SLR
		)			
NEMOURS	FOUNDATION,	)			
		)			
	Defendant.	)			

# MEMORANDUM ORDER

# I. INTRODUCTION

Plaintiffs Michael and Gabriela Yong, as parents, guardians, and next of friends of Tiffany Yong ("Tiffany"), filed this action on February 21, 2002, against defendant Nemours

Foundation. Plaintiffs are seeking special and general damages for brain injuries sustained by Tiffany during a Fontan cardiac procedure performed on October 5, 2000, as a result of the negligent acts or omissions of defendant's employees. (D.I. 56 at 3-4) On March 11, 2004, plaintiffs amended their complaint to include the claim that defendant failed to provide plaintiffs with sufficient information to obtain their informed consent.

(D.I. 55, Ex. A at 2) Plaintiffs are residents of Ireland and citizens of the Netherlands. Defendant is incorporated under the

laws of Florida and conducts business in Delaware. The amount in controversy exceeds the sum of \$75,000, therefore, the court has jurisdiction over plaintiffs' claims pursuant to 28 U.S.C. § 1332(a)(2).

Currently before the court is defendant's motion for summary judgment pursuant to Federal Rule of Civil Procedure 56(b).

(D.I. 55) For the reasons stated below, defendant's motion shall be denied.

#### II. BACKGROUND

Plaintiffs Michael and Gabriela Young are husband and wife and the natural parents of Tiffany Young ("Tiffany"). (D.I. 55, Ex. A) Tiffany was born on October 5, 1988 with complex congenital heart defects, including a single pumping chamber, a single left ventricle and transposition of the three major pulmonary arteries, for which she underwent numerous cardiac surgeries throughout her early childhood. (Id. at 1) When Tiffany was six weeks old, she underwent a banding procedure to obstruct the artery leading to her lungs. Tiffany also had two Fontan variation operations to remove the obstruction between the main pumping chamber and the aorta. Tiffany's post operative

<sup>&</sup>lt;sup>1</sup>The artery leading to Tiffany's lungs arose directly from the main pumping chamber of her heart and was initially unrestricted. (D.I. 55, Ex. E)

<sup>&</sup>lt;sup>2</sup>The main artery to Tiffany's body arose off a small outlet chamber of her heart and was obstructed both between the main pumping chamber and the outlet chamber, and the outlet chamber

recovery from the second of these procedures was stormy and prolonged due to her heart muscle's response to the effects of the bypass operation. (Id. at Ex. E)

In March of 2000, Tiffany's doctors in London advised against a Fontan procedure due to the risks associated with the procedure. (D.I. 56, Ex. E-H) They believed that it would be difficult to regulate the pulmonary blood flow and that it was inadvisable to attempt to directly relieve the obstruction a third time. They were also concerned with Tiffany's "very difficult postoperative course" and warned that there was a significant risk of unrecoverable brain or neurological damage, including a one in four chance of death. (Id.) In that same month, plaintiffs telephoned Doctor Norwood, a pediatric cardiac surgeon working for defendant. Plaintiffs briefly explained Tiffany's congenital defects to Doctor Norwood, including information from the March 2000 letters, to which Dr. Norwood responded with a brief description of the procedure and an assurance that he "can fix it" without ever examining Tiffany. (D.I. 60 at B-53)

On April 3, 2000, Tiffany successfully underwent the first

itself below the aortic valve. (D.I. 56, Ex. E)

<sup>&</sup>lt;sup>3</sup>After a cardiac catheterization was performed on Tiffany, Doctor Taylor and Doctor de Leval sent letters to plaintiffs advising against the Fontan procedure and proposing alternative courses of conduct. (D.I. 56, Ex. E-F)

part of a two-part Fontan procedure at the defendant's Alfred I. duPont Hospital for Children ("AIDHC"). (D.I. 56 at 3) On October 2, 2000, Tiffany was admitted into defendant's hospital for the second part of the Fontan cardiac surgical procedure.

(Id.) On October 4, 2000, plaintiffs signed a Consent for Surgery and Anesthesia Form. (D.I. 56, Ex. G)

On October 5, 2000, Tiffany underwent the second part of the Fontan surgical procedure. The cardiac procedure was performed under the direction of William I. Norwood, M.D., a physician employee of defendant. (D.I. 55) The anesthesia for the procedure was provided by Ellen A. Spurrier, M.D., an anesthesiologist under defendant's employ. The procedure required that Tiffany be placed in deep hypothermic circulatory arrest for approximately forty-five minutes. The deep hypothermic circulatory arrest required that Tiffany's body be cooled down to twenty degrees centigrade using cardiopulmonary

<sup>&</sup>lt;sup>4</sup>The consent form provided the diagnosis as single ventricle and transposition of great arteries and the surgical procedure as Fontan completion. The doctor was identified as Norwood but the form was signed by Dr. Spurrier. The form gave consent to the named physician and his associates to modify the original procedure and administer drugs or blood in the case of unforeseen conditions. It also stated that the risks, alternatives and possible consequences of the procedure were explained and understood by the patient. (D.I. 56, Ex. G)

<sup>&</sup>lt;sup>5</sup>Deep hypothermic circulatory arrest provides the surgeon with a fairly bloodless operative field, so that the surgeon can operate on the heart without blood flow interfering with his/her ability to recognize and correct what is needed. (D.I. 55, Ex. D at 44)

bypass for approximately twenty minutes.<sup>6</sup> (D.I. 66 at B-117)
When Tiffany's procedure was commenced, she had been cooled down
for thirteen minutes and had a nasal temperature of twenty-one
degrees centigrade, an esophageal temperature of fifteen degrees
centigrade, and a rectal temperature of twenty-six degrees
centigrade. Tiffany's operation took sixty-seven minutes. (Id.
at B-29,30)

On October 6, 2000, roughly twenty-four hours after the operation, Tiffany had not regained consciousness indicating some abnormal brain function. There was evidence of seizure type activity which was treated with Ativan, to decrease the irritability of the central nervous system and the expression of seizures. (Id. at B-119) It was later determined that Tiffany suffered a middle cerebral artery infarction. (D.I. 56 at 3) Plaintiffs were not informed of Tiffany's brain trauma until three days after the procedure was performed. Doctor Norwood attributed the cause of Tiffany's injury to the "inadequate delivery of nutrients to cells to meet metabolic demands, oxygen

<sup>&</sup>lt;sup>6</sup>Cardiopulmonary bypass requires the removal of the patient's blood, oxygenating the blood in a heart-lung machine, and pumping the oxygenated blood back into any large arterial branch of the patient's body. (D.I. 66 at B-117) The body temperature is monitored by three temperature probes placed in the rectal, nasopharyngeal, and esophageal areas of the patient's body. (Id. at B-48) Once the physician determines that the optimum temperature has been reached, the surgical procedure is begun. Upon completion of the surgery, the patient is warmed back up to thirty-seven degrees centigrade. (Id. at B-49)

being one of those." (D.I. 66 at B-120) Tiffany was kept at AIDHC for four months until her discharge in February of 2001. (D.I. 56 at 3)

On February 21, 2002, plaintiffs brought this action against defendant for the negligent acts and omissions of the defendant, acting through its physician employees and other agents, servants, and employees. (D.I. 55, Ex. A at 2) Plaintiffs claim that the negligent acts and omissions of defendant departed from the acceptable standards of care. They claim that, as a direct and proximate cause of those acts, Tiffany suffered a deprivation of oxygen to her brain resulting in severe and permanent brain damage, as well as permanent pain, suffering, disability, and medical expenses. (Id.) Plaintiffs further allege that defendant failed to provide them with thorough and complete information, prior and subsequent to the procedure, to obtain their informed consent. (D.I. 55, Ex. A at 2) Plaintiffs have retained two experts in support of their negligence and informed consent claims: Chris A. Kittle, M.D., an anesthesiologist, and Neil Novin, M.D., a surgeon. (D.I. 60 at B-113, 114, 115)

Defendant argues that Dr. Kittle is not a qualified expert as to either the negligence or the informed consent claims.

(D.I. 55) It contends that Dr. Kittle fails to provide any legally sufficient opinions that defendant deviated from its standard of care or was the cause of Tiffany's injuries. (Id. at

2) It further claims that plaintiffs received adequate information for informed consent and their expert failed to opine whether the alleged failure of informed consent caused Tiffany's injuries. (D.I. 56) Defendant claims that pursuant to Federal Rule of Civil Procedure 56(b), it is entitled to summary judgment.

#### III. STANDARD OF REVIEW

A court shall grant summary judgment only if "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c). The moving party bears the burden of proving that no genuine issue of material fact exists. See Matsushita Elec. <u>Indus. Co. v. Zenith Radio Corp.</u>, 475 U.S. 574, 586 n.10 (1986). "Facts that could alter the outcome are 'material,' and disputes are 'genuine' if evidence exists from which a rational person could conclude that the position of the person with the burden of proof on the disputed issue is correct." Horowitz v. Fed. Kemper <u>Life Assurance Co.</u>, 57 F.3d 300, 302 n.1 (3d Cir. 1995) (internal citations omitted). If the moving party has demonstrated an absence of material fact, the nonmoving party then "must come forward with 'specific facts showing that there is a genuine issue for trial.'" Matsushita, 475 U.S. at 587 (quoting Fed. R.

Civ. P. 56(e)). The court will "view the underlying facts and all reasonable inferences therefrom in the light most favorable to the party opposing the motion." Pa. Coal Ass'n v. Babbitt, 63 F.3d 231, 236 (3d Cir. 1995). The mere existence of some evidence in support of the nonmoving party, however, will not be sufficient for denial of a motion for summary judgment; there must be enough evidence to enable a jury reasonably to find for the nonmoving party on that issue. See Anderson v. Liberty
Lobby, Inc., 477 U.S. 242, 249 (1986). If the nonmoving party fails to make a sufficient showing on an essential element of its case with respect to which it has the burden of proof, the moving party is entitled to judgment as a matter of law. See Celotex Corp. v. Catrett, 477 U.S. 317, 322 (1986).

# IV. DISCUSSION

# A. Medical Negligence

# 1. Competence of Dr. Chris Kittle

When objections are made to an expert witness' qualifications, a plaintiff is required to establish that his/her expert is qualified to give expert medical testimony under the standards set forth in 18 Del.C. § 6854. Whether a plaintiff establishes the statutory criteria is a determination to be made by the court. <u>Burkhart v. Davies</u>, 602 A.2d 56, 59 (Del. 1991).

The Delaware expert witness statute sets forth a two-prong test of competency for expert medical witnesses. Under §

2854(a), a person "familiar with that degree of skill ordinarily employed in the community or locality where the alleged malpractice occurred" may be found competent. Alternatively a witness may qualify under § 2854(b). This subsection establishes three conditions which an out-of-state physician must meet in order to be presumed competent. First, the physician must have been in active practice for at least the preceding five years. Second, the physician must practice in a state contiguous to Delaware, within seventy-five miles of Dover. Finally, the standard of care in the locality where the physician practices must be equivalent to that of the locality where the alleged malpractice occurred. In addition, in determining the competency of an expert medical witness, the court may consider the following factors: 1) direct observation in Delaware; 2) study in Delaware (as a medical student on rotation, intern or resident); 3) care of Delaware patients referred by Delaware physicians; 4) teaching of students who have dispersed to Delaware; 5) reading of Delaware medical journals, reports, journals, etc.; 6) consultation with Delaware physicians; and 7) attendance at meetings with Delaware physicians. Id.

During discovery, plaintiffs identified Dr. Kittle and Dr. Novin as the experts who would testify as to the standard of care required during cardiac bypass surgery and to opine whether that standard of care had been breached during Tiffany's October 5,

2000 operation. Defendant only challenges the qualifications of Dr. Kittle. Dr. Kittle is a staff cardiac anesthesiologist of the open heart surgical team at the Christiana Care Health System in Newark, Delaware. (D.I. 55, Ex. B) He has been a practicing anesthesiologist in Delaware since 1982. Dr. Kittle graduated from the Jefferson Medical College, was an intern at the former Medical Center of Delaware, a resident at Stanford University Medical Center, and performed his fellowship at the University of Pennsylvania Cardiac Anesthesia and Intensive Care Center. He holds medical licenses in California, Delaware, and Pennsylvania, as well as in the National and American Boards of Anesthesiology. Dr. Kittle is a member of numerous committees in the Christiana Care Health System, including the Cardiac Surgery Quality Improvement Committee. (Id.) Lastly, he has offered lectures and presentations in Delaware, thus educating students and doctors on anesthesiological issues, including the impact of anesthesia on the neurological system. (Id.)

Dr. Kittle possesses the familiarity necessary through experience and direct observations in Delaware accumulated over a period of twenty years. When he began his staff position at the Christiana Hospital, approximately 10 to 15 percent of his work involved pediatric surgery, although none involved cardiac surgery. (D.I. 60 at B-2) In 1991, Dr. Kittle joined the cardiac anesthesia team where approximately 100 percent of his

practice involved cardiac surgery. (Id. at B-3) The cardiac anesthesia team performed approximately one thousand open heart surgeries a year, forty or fifty of those cases were related to pediatric patients. As a result, Dr. Kittle was responsible for one third or approximately seven pediatric cardiac cases per year. (Id. at B-4)<sup>7</sup> Overall, in his career as an anesthesiologist, Dr. Kittle has been responsible for approximately seventy pediatric cardiac surgeries, including ten to fifteen cardiac Fontan procedures and five procedures involving deep hypothermic cardiopulmonary bypass.<sup>8</sup> (Id. at B-8,9)

In conclusion, Dr. Kittle is a qualified medical expert.

Accordingly, defendant's motion for summary judgment is denied in this regard.

# 2. Dr. Kittle's Opinion

Under Delaware law, when a plaintiff alleges medical negligence, plaintiff must produce expert medical testimony that details: (1) the applicable standard of care; (2) the alleged deviation from that standard; and (3) the causal link between the deviation and the alleged injury. Burkhart v. Davies, 602 A.2d

<sup>&</sup>lt;sup>7</sup>When defendant's cardiac surgery program was started about four to five years ago, Dr. Kittle's employer no longer performed pediatric cardiac surgery. (<u>Id.</u> at B-5)

<sup>&</sup>lt;sup>8</sup>Dr. Kittle has worked on fifty cases involving the deep hypothermic cardiopulmonary bypass procedure but only five involved pediatric patients.

56, 59 (Del. 1991). In the absence of competent medical testimony establishing negligence, defendant is entitled to summary judgment. Burkhart, 602 A.2d at 60. Moreover, when there has been adequate time for discovery and the record unambiguously reflects that plaintiff's allegations are not and will not be supported by any expert testimony, defendant's motion for summary judgment is proper. Defendant's motion for summary judgment does not require the support of an expert's affidavit proving conformance to community standards. Id.

Here, plaintiffs allege that Dr. Kittle's deposition attributes Tiffany's brain injury, within a reasonable degree of medical certainty, to the circulatory arrest time utilized during the Fontan procedure performed by defendant's employees. (D.I. 60 at B-113) Dr. Kittle's deposition provides evidence that the lack of communication between the surgical team and the anesthesia team before and during the procedure was the proximate cause of Tiffany's brain injury. (Id.) Dr. Kittle testified that, in his medical opinion, defendant deviated from the standard of care in cooling Tiffany's body for thirteen minutes rather than the customary twenty and in not cooling Tiffany's body to a rectal temperature of twenty degrees centigrade before

<sup>&</sup>lt;sup>9</sup>There is a presumption of negligence in cases where foreign objects are unintentionally left in the patient's body, an explosion or fire occurs during treatment, or the surgery was performed on the wrong patient or organ. 18 Del. C. §§ 6853 (2004).

initiating the deep hypothermic cardiopulmonary arrest. 10 He further testified that the length of Tiffany's deep hypothermic cardiopulmonary arrest was "longer than usually accepted in terms of what we know about the instance of neurologic damage and death following prolonged deep hypothermic circulatory arrest...

You're pushing the limits when you're out at sixty-seven minutes on what the chances are of waking up normal." (D.I. 60 at B-30)

Dr. Kittle indicated that the surgeon decides whether to exceed the forty-five minute threshold in order to complete the goals of the operation, if the procedure proves to be more complex or involved than anticipated. However, he found that the medical record contained only the standard dictation that everything went fine during the operation. 11 (Id. at B-31)

Dr. Kittle's expert medical testimony provides a direct nexus between the circulatory arrest time and the length and temperature of cooling to Tiffany's anoxic brain injury, therefore, plaintiffs have satisfied their burden of proof on the issue of causation. Accordingly, defendant's motion for summary judgment is denied.

<sup>&</sup>lt;sup>10</sup>Dr. Kittle bases this opinion on his own personal experience and citing the reference in the Cardiopulmonary Bypass pages.

<sup>&</sup>lt;sup>11</sup>Dr. Kittle testified that he would have liked to see in the medical record some indication that the surgical repair was complex or more involved than anticipated to justify pushing the limits of what is known to be safe in order to complete the operation.

# B. Informed Consent

Legal-medical jurisprudence requires that a physician obtain the consent of a patient before performing surgery unless the need for such consent is obviated by an emergency which places the patient in imminent danger and makes it impractical to secure such consent. <u>Dunham v. Wright</u>, 423 F.2d 940, 941 (3d Cir. 1970). Effective consent is one made after the patient has been advised of the possible consequences and risks inherent in the particular operation and, therefore, imposes upon a physician the duty to disclose to his/her patient the possible adverse results of the operation. <u>Id.</u> at 944. It may also be necessary that the patient be informed of the alternative treatments available to him/her and the inherent dangers and possibilities of success of such alternatives. Marino v. Gnaden Huetten Memorial Hosp., 749 F.2d 162, 168 (3d Cir. 1984). A patient has the right to be informed of all the facts, risks and alternatives that a reasonable person in the plaintiff's situation would deem significant in making a decision to undergo the recommended treatment. 18 Del. C. § 6852 (2004).

The theory behind the informed consent doctrine is that every patient has the right and responsibility to determine whether to take the risk of the corrective surgery. It is no defense that the patient gave consent, if the consent was not given with a true understanding of the nature of the operation to

be performed, the seriousness of it, the organs of the body involved, the disease or incapacity to be cured, and the possible results. <u>Dunham</u>, 423 F.2d at 945. The burden of proof is on the plaintiff to demonstrate that the health care provider failed to supply information "customarily given" by other "licensed health care providers with similar training and/or experience in the same or similar health care communities as that of the defendant at the time of treatment, procedure or surgery." <u>Barriocanal v. Gibbs</u>, 433 A.2d 1051, 1172 (Del. Super. Ct. 1981). It is for the jury to determine whether, under all the circumstances, the plaintiff has sustained this burden and proved by a preponderance of the evidence that the consent was not informed. <u>Dunham</u>, 423 F.2d at 946.

Here, the record discloses uncontradicted evidence of the existence of alternative procedures. There is no evidence that defendant disclosed any alternatives, possible risks, or explained the procedure to plaintiffs. In fact, all the record indicates is that plaintiffs signed an informed consent form the day prior to the surgery. (D.I. 56, Ex. G) It is uncontested that plaintiffs were informed of the severe risks of death or brain injury involved in the Fontan procedure and of possible alternatives, but these were given to plaintiffs by Tiffany's London doctors prior to plaintiffs' consultation with

defendant. 12 (Id. at Ex. E, F) It is a proper question for the jury to determine whether the grave information provided by the London doctors prior to defendant's assurance that "I can fix that" suffices for informed consent.

For the reasons previously stated, defendant's motion for summary judgment is denied.

# V. CONCLUSION

At Wilmington, this 1st day of December, 2004 for the reasons stated;

IT IS ORDERED that defendant's motion for summary judgment is denied. (D.I. 55)

Sue L. Robinson
United States District Judge

<sup>&</sup>lt;sup>12</sup>The March 6, 2000, letter from Dr. Taylor identified the significant risk of damage to Tiffany's brain and nervous system which she might not fully recover from and a one in four chance that Tiffany may not even survive the procedure. (D.I. 66, Ex. E)